Applicant: Richard A. Mathies et al

US Serial No: 09/927,431

REMARKS

In the Office Action of September 3, 2003, the Examiner rejected claims 5 and 6 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claims 5 and 6 to overcome this rejection.

The Examiner also rejected claims 1, 2 and 5 under 35 U.S.C. §102(e) as anticipated by US Patent 5,593,838 to Zanzucchi et al. Applicants respectfully disagree with these rejections because there are important differences between the teaching provided in US Patent 5,593,838 and claims 1, 2, and 5. Zanzucchi does not disclose a microfluidic device with a cavity and a body that includes at least first and second planar members, wherein the first planar member has a first surface and a well disposed in the first surface, the second planar member has a second substantially planar surface, and wherein the second surface is being mated to the first surface whereby the well forms the cavity. Furthermore, Zanzucchi does not disclose a temperature sensor deposited on said second surface and located inside said cavity when the second surface is mated with the first surface.

The Examiner also rejected claims 7-9 under 35 U.S.C. §103(a) as being unpatentable over US Patent 5,593,838 to Zanzucchi et al. stating that it is "obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device." Applicants respectfully disagree with these unsupported statements. To achieve the very small volumes in a microfluidic device is certainly not obvious. Applicants believe that they are the first to successfully design such microfluidic device with a reaction chamber capable of handling, transferring and processing such small volumes for successfully performing reactions in the reaction chamber (such as performing PCR). Therefore claims 7, 8 and 9 are novel and non-obvious.

The present claim 1 is directed to a miniature device including a body having a reaction chamber constructed to receive a liquid, and a vent in fluid communication with the reaction chamber. The device also includes a resistive heater electrically connected to a power source for applying power to the heater, and a temperature sensor disposed

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on a surface of the body for determining a temperature within the reaction chamber. A computer monitors the temperature and operates the power source to selectively apply the power to the heater in order to facilitate a reaction in the reaction chamber. Importantly, the vent enables removal of gas from the reaction chamber thereby preventing a temperature variation in the liquid during heating.

The novel device of claim 1 has important advantages because it avoids during processing unwanted bubbles that undergo expansion and contraction when increasing or decreasing the processing temperature. Furthermore, the bubbles prevent uniform temperature distribution in the fluid and this in turn negatively impacts the reaction in the reaction chamber. These are important drawbacks that the present inventors noticed and then eliminated by the present design. Neither Zanzucchi nor any other reference cited by the Examiner discloses this novel design.

Applicants also included new claims 14 through 26 fully supported by the pending specification. Specifically, independent claim 20 is directed to a miniature device including a body comprising at least two reaction chambers arranged in parallel, wherein each reaction chamber is constructed to separately receive a liquid and each reaction chamber is in fluid communication with a vent. The miniature device includes at least two resistive heaters electrically connected to a power source for applying power, wherein each heater is constructed to deliver heat to one reaction chamber, and at least two temperature sensors for determining separately a temperature within each reaction chamber. The device facilitates separate reactions in the reaction chambers by also controlling and monitoring the temperature and operating the power source to selectively apply the power to each the heater. Importantly, each vent enables removal of gas from the corresponding reaction chamber thereby preventing a temperature variation in the liquid during the reaction. This novel device is not disclosed by Zanzucchi or any other reference cited by the Examiner.

Accordingly, all claims are now in condition for allowance and such action is respectively requested. Should there be any outstanding issue left, the Examiner is respectfully invited to call the undersigned to resolve such issues.

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Enclosed is a Petition for Extension of Time. Please apply any charges or credits to the Deposit Account No. 01-0431.

Respectfully submitted,

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